

161

3743

MAIL

## THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David O'Leary, et al.

Examiner: Nihir Patel

Serial No.: 09/888,199

Group Art Unit: 3743

Filing Date: June 23, 2001

Docket Number: 56327-149 (IVAL-127-1)

Title: RESERVOIR PRESSURE SYSTEM FOR MEDICAMENT INHALER

CERTIFICATE OF MAILING (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Date: 4-19-2005W. E. W. C. H. E. N

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RECEIVED****APR 26 2005**

TECHNOLOGY CENTER R3700

**PETITION TO WITHDRAW HOLDING OF ABANDONMENT BASED ON FAILURE**  
**TO RECEIVE OFFICE ACTION**

Sir:

Applicants respectfully petition to withdraw holding of abandonment based on failure to receive Office Action in connection with the above-referenced application.

Applicants filed a request of Change of Correspondence Address in Patent Application on June 25, 2002 to change correspondence address to the address of a counsel for Applicants: Mark G. Lappin, McDermott, Will & Emery, 28 State Street, Boston, MA 02109 (the Amended Correspondence Address). Copies of the request and a return postcard, which had been stamped by the USPTO with a receiving date of July 2, 2002, have been enclosed herewith as EXHIBIT A.

An Office Action addressed to Applicants' assignee, whose address is **different** from the above-mentioned correspondence address, appears to have been mailed on August 13, 2002, based on "mail date" set forth on page 1 of the Office Action (copy enclosed as EXHIBIT B). Applicants hereby certify that, at the Amended Correspondence Address, Applicants did not receive the Office Action within six months from the mailing date of the Office Action. Applicants have enclosed herewith a docketing record (as EXHIBIT C) at the above-mentioned correspondence address showing that no Office Action had been received within six months from the mailing date of the Office Action for the subject application. If the Office Action were received within six months from the mailing date (which is August 13, 2002) of the Office

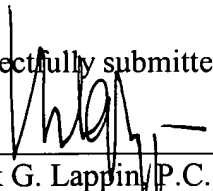
Action, a receiving date or a three month period reply due date would be set in the counsel's docketing record. However, from the enclosed docketing record, it is clear that from August 5, 2002 to October 30, 2002, there is no receiving date or reply due date set for the Office Action. In the docketing entry "Office Action Received Yet?" as highlighted in the docketing record, Applicants estimated that a first Office Action for the subject application would be received by December 23, 2002, but the docketing record shows that no Office Action was received by that date. (A hypothetical date 01-Jan-1930 was recorded in the column of "Action Taken" as required by the docketing software. If the Office Action was received by December 23, 2002, a real receiving date would be recorded instead of the hypothetical date.) The docketing record further shows that by March 23, 2003, no Office Action had been received by Applicants' counsel at the Amended Correspondence Address.

On May 20, 2003, the undersigned counsel for Applicants first learned of the Office Action from the above identified Examiner during an interview with the Examiner at the USPTO in a related application, and at that time, received from the Examiner a copy of the Office Action. A response to the Office Action was filed June 2, 2003 together with a Petition for Revival (a copy of which is enclosed as EXHIBIT D), since the six-month statutory period for response to the Office Action had expired on February 13, 2003. Since the failure to file a timely and proper response to the Office Action dated August 13, 2002 is due to not receiving the Office Action at the Amended Correspondence Address, Applicants respectfully request withdrawal of holding of abandonment of the subject application.

It is believed no fees are due with respect to the submission of this paper. However, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 50-113.

Date: 4/18/05

Respectfully submitted,

  
\_\_\_\_\_  
Mark G. Lappin/P.C.  
Registration No.: 26,618  
McDERMOTT WILL & EMERY LLP  
28 State Street  
Boston, Massachusetts 02109  
Telephone: (617) 535-4043  
Facsimile: (617) 535-3800



## EXHIBIT A

**RECEIVED**

**APR 26 2005**

**TECHNOLOGY CENTER R3700**

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APR 26 2005

TECHNOLOGY CENTER R3700

Title: RESERVOIR PRESSURE SYSTEM...

Serial No. 09/888,199

Applicant D'LEARY

In the above matter, the following have been received by the US Patent and Trademark Office on the date stamped hereon.

- ☐ Express Mail Label No. \_\_\_\_\_
- ☐ Application incl. \_\_\_\_\_ pages ( \_\_\_\_\_ Design)
- \_\_\_\_\_ pp. of specification
- \_\_\_\_\_ pp. of claims (# of claims - \_\_\_\_\_)
- \_\_\_\_\_ pp. of abstract
- \_\_\_\_\_ sheets of drawings; Figs. \_\_\_\_\_
- ☐ formal ☐ informal
- ☐ Provisional Application Cover Sheet
- ☐ Declaration / Power of Attorney ( \_\_\_\_\_ Unsigned)
- ☐ Verified Statement Claiming Small Entity Status
- ☐ Copy of Notice to File Missing Parts
- ☐ Request for filing CPA; 37 CFR 53(d)
- ☐ IDS, PTO-1449, and \_\_\_\_\_ references (Supp. \_\_\_\_\_)
- ☐ Certificate of Mailing under 37 CFR 1.8(a)
- ☐ Response to Office Action/Restriction Req.
- ☐ Petition for \_\_\_\_\_ month extension of time
- ☐ Assignment and Cover Sheet
- ☐ Amendment (☐ Preliminary; ☐ After Final)
- ☐ Notice of Appeal
- ☐ Appellant's Brief (triplicate) (☐ Reply Brief)
- ☐ Letter to Chief Draftsperson
- ☐ Issue Fee / ☐ Maintenance Fee Transmittal
- ☐ Sequence listing; ☐ Diskette
- ☐ Transmittal Letter
- ☐ Check for \$ \_\_\_\_\_; check # \_\_\_\_\_
- ☐ Deposit Account Authorization \$ \_\_\_\_\_

☒ other: CHANGE OF CORRESPONDENCE ADDRESS

☐ other: \_\_\_\_\_

Mailing Date: 6/25/02

Docket No. 14C 09314-US

Atty/paralegal/secy: JS/SCM

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JUL 8 2002

MWB/E

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: O'Leary, David  
Serial No.: 09/888,199  
Filing Date: 23 June 2001  
Docket Number: NH00031A-USA  
Title: RESERVIOR PRESSIRE SYSTEM  
FOR MEDICAMENT INHALER

**BOX PATENT ADDRESS CHANGE**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

CHANGE OF CORRESPONDENCE ADDRESS IN PATENT APPLICATION

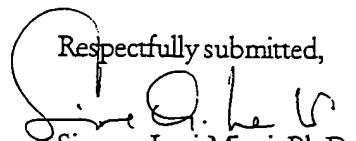
Please change the correspondence address of the above-identified patent application to:

Mark Lappin, Esq.  
McDermott, Will & Emery  
28 State Street  
Boston, MA 02109  
Tel.: 617.535.4043  
Fax.: 617.535.3800

It is certified that the person whose signature appears below has the authority to change the correspondence address for this patent application.

If there are any questions, please call the undersigned at the telephone number indicated below.

Respectfully submitted,

  
Simona Levi-Minzi, Ph.D.  
Registration No. 43,750  
Attorney for Applicants


IVAX CORPORATION  
4400 Biscayne Boulevard  
Miami, Florida 33137  
Tel: (305) 575-6061  
Fax: (305) 575-6045

Date: June 25, 2002

CERTIFICATE OF MAILING (37 C.F.R. § 1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231 on the date indicated below.

Date: 6/25/02

By:   
Jared G. Silberhorn

✓

Title: RESERVOIR PRESSURE SYSTEM...

Serial No. 09/888,199

Applicant D'Leary

In the above matter, the following have been received by the US Patent and Trademark Office on the date stamped hereon.

- |  |  |
|--|--|
| <input type="checkbox"/> Express Mail Label No. _____                    | <input type="checkbox"/> Certificate of Mailing under 37 CFR 1.8(a)  |
| <input type="checkbox"/> Application incl. _____ pages (____ Design)     | <input type="checkbox"/> Response to Office Action/Restriction Req.  |
| _____ pp. of specification   | <input type="checkbox"/> Petition for ____ month extension of time   |
| _____ pp. of claims (# of claims - _____)                                | <input type="checkbox"/> Assignment and Cover Sheet  |
| _____ pp. of abstract  | <input type="checkbox"/> Amendment ( <input type="checkbox"/> Preliminary; <input type="checkbox"/> After Final) |
| _____ sheets of drawings; Figs. _____                                    | <input type="checkbox"/> Notice of Appeal  |
| <input type="checkbox"/> formal <input type="checkbox"/> informal        | <input type="checkbox"/> Appellant's Brief (triplicate)( <input type="checkbox"/> Reply Brief)                   |
| <input type="checkbox"/> Provisional Application Cover Sheet             | <input type="checkbox"/> Letter to Chief Draftsperson  |
| <input type="checkbox"/> Declaration / Power of Attorney (____ Unsigned) | <input type="checkbox"/> Issue Fee / <input type="checkbox"/> Maintenance Fee Transmittal                        |
| <input type="checkbox"/> Verified Statement Claiming Small Entity Status | <input type="checkbox"/> Sequence listing; <input type="checkbox"/> Diskette                                     |
| <input type="checkbox"/> Copy of Notice to File Missing Parts            | <input type="checkbox"/> Transmittal Letter  |
| <input type="checkbox"/> Request for filing CPA; 37 CFR 53(d)            | <input type="checkbox"/> Check for \$ _____; check # _____   |
| <input type="checkbox"/> IDS, PTO-1449, and ____ references (Supp. ____) | <input type="checkbox"/> Deposit Account Authorization \$ _____  |

☒ other: CHANGE OF CORRESPONDENCE ADDRESS

☐ other: \_\_\_\_\_

Mailing Date: 6/25/02 Docket No. 144931A-US Atty/paralegal/secy: J/S/SCM

## EXHIBIT B



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,199	06/23/2001	David O'Leary	NHC0031A-USA	8435

7590 08/13/2002  
IVAX Corporation  
4400 Biscayne Boulevard  
Miami, FL 33137

EXAMINER

PATEL, NIHIR B

ART UNIT PAPER NUMBER

3743

(DATE MAILED: 08/13/2002)

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED  
MAY 20 2003  
Rec'd from Exam - Gwent to M. Loppin  
MW&E ET PTO

DOCKETED  
PCN  
6/30/03 Petition to Re-examine  
6/30/03 Amendment



<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/888,199	O'LEARY, DAVID	
	Examiner	Art Unit	
	Nihir Patel	3743	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Specification*

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative. The term "A new and improved" should not be disclosed in the abstract.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 through 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Referring to claim 1, there is insufficient antecedent basis for

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limitations “the dispensing port”, “the sealed reservoir”, “the pressure relief port”, “the channel”, and “the recess”.

Referring to claims 2 and 7, there is insufficient antecedent basis for limitations “the cup assembly” and “the reservoir”.

Referring to claim 3, there is insufficient antecedent basis for limitations “the reservoir” and “the pressure relief port”.

Referring to claim 4, there is insufficient antecedent basis for limitations “the cup assembly”, “the channel”, “the cup”, and “the recess”.

Referring to claim 5, there is insufficient antecedent basis for limitations “the sled”, “the pressure relief port”, and “the dispenser port”.

Referring to claim 6, there is insufficient antecedent basis for limitations “the cup assembly”, “the cup”, “the cup sled”, and “the reservoir”.

Referring to claim 8, there is insufficient antecedent basis for limitations “the cup assembly”, “the channel”, and “the yoke”.

Referring to claim 9, there is insufficient antecedent basis for limitations “the cup spring biasing the cup assembly”, “the recess”, “the dispensing port”, and “the reservoir”.

Referring to claim 10, there is insufficient antecedent basis for limitations “the yoke”, “the recess”, “the cup assembly”, and “the dispensing port”.

Referring to claim 11, there is insufficient antecedent basis for limitations “the yoke” and “the cam”.

Referring to claim 12, there is insufficient antecedent basis for limitations “the cam”, “the yoke”, “the recess”, “the dispensing port”, and “the cup assembly”.

Referring to claim 13, there is insufficient antecedent basis for limitations “the reservoir”, “the yoke”, and “the bellows”.

Referring to claim 14, there is insufficient antecedent basis for limitations “the mouthpiece”, “the cover”, and “the yoke”.

Referring to claim 15, there is insufficient antecedent basis for limitations “the cam”.

Referring to claim 16, there is insufficient antecedent basis for limitations “the reservoir”.

Referring to claim 17, “the recess”, “the cup assembly”, “the dispensing port”, “the bobbin”, “the ribbon”, “the spool”, and “the pawl”.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4 through 7, 9, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaeffer et al. U.S. Patent No. 6,065,471. Referring to claim 1, Schaeffer discloses an inhalation device that comprises a sealed reservoir (6) including a dispensing port (13) (Refer to figures 1, 3, column 3 lines 15 through 20, and column 4 lines 15 through 20; a channel communicating with the dispensing port and including a pressure relief port (Refer to figures 3 and 4, and column 4 lines 15 through 25); a conduit providing fluid communication between an interior of the sealed reservoir and the pressure relief port of the channel (Refer to figures 3 and 4 and column 4 lines 15 through 25); a cup assembly movably received in the channel and including a recess (22) adapted to receive medicament when aligned with the

dispensing port, a first sealing surface adapted to seal the dispensing port when the recess is unaligned with the dispensing port, and a second sealing surface adapted to sealing the pressure relief port when the recess is aligned with the dispensing port and unseal the pressure relief port when the recess is unaligned with the dispensing port (Refer to figures 1 through 9 and column 4 lines 40 through 65).

Referring to claim 2, Schaeffer shows that the cup assembly includes a sealed spring (25) biased the first sealing surface against the reservoir (Refer to figure 7 and column 4 lines 50 through 55).

Referring to claim 4, Schaeffer shows that the cup assembly includes a cup received in a cup sled movable within the channel, the cup defining the recess and the first sealing surface and the sled defining the second sealing surface (Refer to figures 7 and 8 and column 4 lines 40 through 65).

Referring to claim 5, Schaeffer shows that the sled defines an indentation adapted to align with and unseal the pressure relief port when the first sealing surface is aligned with the dispenser port (Refer to figure 10 and column 5 lines 1 through 10).

Referring to claim 6, Schaeffer shows a cup assembly that includes a sealing spring (25) between the cup and the cup sled, biasing the first sealing surface of the cup against the reservoir (Refer to figures 7 and 8 and column 4 lines 40 through 65).

Referring to claim 7, Schaeffer shows that the channel extends linearly and the cup assembly is movable in opposing directions within the channel (Refer to figures 1 and 7 and column 4 lines 40 through 65).

Referring to claim 9, Schaeffer shows that the cup spring biases the cup assembly to a position wherein the recess is unaligned with the dispensing part of the reservoir (Refer to figures 7 and 8 and column 4 lines 40 through 65).

Referring to claim 16, Schaeffer shows that the reservoir includes a volume of dry powdered medicament (Refer to the abstract).

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. U.S. Patent No. 6,065,471 in view of Whaley et al. U.S. Patent No. 6,029,661.

Schaeffer discloses the applicant's invention as claimed with the exception of providing a reservoir that includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed.

Whaley discloses a powder dispenser that does provide a reservoir that includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed. Therefore it would be obvious to modify Schaeffer's invention by providing a reservoir that includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed in order to provide a better flow of the medicament powder when required.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. U.S. Patent No. 6,065,471 in view of Palson et al. U.S. Patent No. 5,119,806.

Referring to claim 9, Schaeffer discloses the applicant's invention as claimed with the exception of providing a yoke movable between at least two positions and including a ratchet engaging the cup assembly and preventing movement of the cup when the yoke is in one of the positions and allowing movement of the cup when the yoke is in another of the positions.

Palson discloses an inhalation device that does provide a yoke movable between at least two positions and including a ratchet engaging the cup assembly and preventing movement of the cup when the yoke is in one of the positions and allowing movement of the cup when the yoke is in another of the positions. Therefore it would be obvious to modify Schaeffer's invention by providing a yoke movable between at least two positions and including a ratchet engaging the cup assembly and preventing movement of the cup when the yoke is in one of the positions and allowing movement of the cup when the yoke is in another of the positions in order to provide a better way to control the amount of medicament powder being delivered.

Referring to claim 10, Schaeffer discloses the applicant's invention as claimed with the exception of providing a push bar that is adapted to align the recess of the cup assembly with the dispensing port upon movement of the yoke to one of the positions.

Palson discloses an inhalation device that does provide a push bar that is adapted to align the recess of the cup assembly with the dispensing port upon movement of the yoke to one of the positions. Therefore it would be obvious to modify Schaeffer's invention by providing a push bar that is adapted to align the recess of the cup assembly with the dispensing port upon movement

of the yoke to one of the positions in order to provide a better way to control the amount of medicament powder being delivered.

Claims 11,12,14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. U.S. Patent No. 6,065,471 in view of MacMichael et al. U.S. Patent No. 6,405,727.

Referring to claim 11, Schaeffer discloses the applicant's invention with the exception of providing at least one movable cam including at least two successive cam surfaces; and a spring biasing the yoke against the cam such that movement of the cam causes the yoke to successively engage the cam surfaces and move the yoke between the at least two positions of the yoke.

MacMichael discloses an inhaler mechanism that does provide at least one movable cam including at least two successive cam surfaces; and a spring biasing the yoke against the cam such that movement of the cam causes the yoke to successively engage the cam surfaces and move the yoke between the at least two positions of the yoke. Therefore it would be obvious to modify Schaeffer's invention by providing at least one movable cam including at least two successive cam surfaces; and a spring biasing the yoke against the cam such that movement of the cam causes the yoke to successively engage the cam surfaces and move the yoke between the at least two positions of the yoke in order to provide a better way to control the amount of medicament powder being delivered.

Referring to claim 12, Schaeffer discloses the applicant's invention as claimed with the exception of providing a cam that includes three successive cam surfaces for moving the yoke between three positions, wherein the ratchet is adapted to hold the recess unaligned with the



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dispensing port when the yoke is in a first and a second of the three positions, and allow movement of the cup assembly when the yoke is in a third of the three positions.

MacMichael discloses an inhaler mechanism that does provide a cam that includes three successive cam surfaces for moving the yoke between three positions, wherein the ratchet is adapted to hold the recess unaligned with the dispensing port when the yoke is in a first and a second of the three positions, and allow movement of the cup assembly when the yoke is in a third of the three positions. Therefore it would be obvious to modify Schaeffer's invention by providing a cam that includes three successive cam surfaces for moving the yoke between three positions, wherein the ratchet is adapted to hold the recess unaligned with the dispensing port when the yoke is in a first and a second of the three positions, and allow movement of the cup assembly when the yoke is in a third of the three positions in order to provide a better way to control the amount of medicament powder being delivered.

Referring to claim 14, Schaeffer discloses the applicant's invention as claimed with the exception of providing a cover movable to open and close the mouthpiece, wherein the at least one cam is secured to the cover for movement therewith, whereby opening and closing the mouthpiece causes the yoke to move between the three positions of the yoke.

MacMichael discloses an inhaler mechanism that does provide a cover movable to open and close the mouthpiece, wherein the at least one cam is secured to the cover for movement therewith, whereby opening and closing the mouthpiece causes the yoke to move between the three positions of the yoke. Therefore it would be obvious to modify Schaeffer's invention by providing a cover movable to open and close the mouthpiece, wherein the at least one cam is secured to the cover for movement therewith, whereby opening and closing the mouthpiece

causes the yoke to move between the three positions of the yoke in order to prevent excessive use of the medicament powder.

Referring to claim 15, Schaeffer discloses the applicant's invention as claimed with the exception of providing a cam this is movable by rotation.

MacMichael discloses an inhaler mechanism that does provide a cam this is movable by rotation. Therefore it would be obvious to modify Schaeffer's invention by providing a cam this is movable by rotation in order to provide a better way to control the amount of medicament powder being delivered.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whaley et al. U.S. Patent No. 6,029,661 as applied to claim 3 above, and further in view of Palson et al. U.S. Patent No. 5,119,806.

Whaley discloses the applicant's invention with the exception of providing a yoke that is arranged to collapse the bellows when the yoke is in the first and the second position.

Palson discloses an inhalation device that does provide a yoke that is arranged to collapse the bellows when the yoke is in the first and the second position. Therefore it would be obvious to modify Whaley's invention by providing a yoke that is arranged to collapse the bellows when the yoke is in the first and the second position in order to provide a better way to control the amount of medicament powder being delivered.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. U.S. Patent No. 6,065,471 in view of Ashley et al. U.S. Patent No. 5,740,792.

Schaeffer discloses the applicant's invention as claimed with the exception of providing an inhaler that comprises a pawl movable along a predetermined path upon movement of the

Art Unit: 3743

recess of the cup assembly from the dispensing port, and a dose counter including a bobbin, a rotatable spool, a rolled ribbon received on the bobbin and rotatable about an axis of the bobbin, the ribbon having indicia thereon successively extending between a first end of the ribbon secured to the spool and a second end of the ribbon positioned on the ribbon, and teeth extending radially outwardly from the spool into the predetermined path of the pawl and the ribbon is advanced onto the spool during the metering of the dose.


Ashley discloses an inhaler for powdered medications with gear-teeth counter assembly that does provide an inhaler that comprises a pawl movable along a predetermined path upon movement of the recess of the cup assembly from the dispensing port, and a dose counter including a bobbin, a rotatable spool, a rolled ribbon received on the bobbin and rotatable about an axis of the bobbin, the ribbon having indicia thereon successively extending between a first end of the ribbon secured to the spool and a second end of the ribbon positioned on the ribbon, and teeth extending radially outwardly from the spool into the predetermined path of the pawl and the ribbon is advanced onto the spool during the metering of the dose. Therefore it would be obvious to modify Schaeffer's invention by providing an inhaler that comprises a pawl movable along a predetermined path upon movement of the recess of the cup assembly from the dispensing port, and a dose counter including a bobbin, a rotatable spool, a rolled ribbon received on the bobbin and rotatable about an axis of the bobbin, the ribbon having indicia thereon successively extending between a first end of the ribbon secured to the spool and a second end of the ribbon positioned on the ribbon, and teeth extending radially outwardly from the spool into the predetermined path of the pawl and the ribbon is advanced onto the spool during the metering of the dose so that one knows the amount of medicament powder is in the reservoir.

*Conclusion*

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP  
July 31, 2002

  
SPE AU 3743  
8/4/02

## EXHIBIT C

# CountryApplications

Clear

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Client-Matter: IVAL

- 0127-1

Family Number: IVAL-0127-1

Sub Matter: 056327-0149

Country:

US

United States of America

Client Ref #:

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Show Only Outstanding Actions

Up

32 Action(s) Due	Due Date	Indicator	Action Taken
Sup IDS basd Search Rep (arb)	05-Aug-2002	Reminder	01-Jan-1930
Sup IDS basd Search Rep (arb)	05-Sep-2002	Reminder	01-Jan-1930
Sup IDS basd Search Rep (arb)	19-Sep-2002	Reminder	01-Jan-1930
Sup IDS basd Search Rep (arb)	30-Sep-2002	Reminder	01-Jan-1930
Sup IDS basd Search Rep FINAL	05-Oct-2002	Final	30-Sep-2002
POSTCARD REC'D BACK PTO	30-Oct-2002	Reminder	18-Oct-2002
Office Action Received Yet?	23-Dec-2002	Due Date	01-Jan-1930
Office Action Received Yet?	23-Mar-2003	Reminder	01-Jan-1930
Amendment	30-May-2003	Due Date	01-Jan-1930
Petition to Revoke	30-May-2003	Due Date	01-Jan-1930
Amendment	13-Jun-2003	Due Date	03-Jun-2003
Petition to Revoke	13-Jun-2003	Due Date	03-Jun-2003
Amendment	20-Jun-2003	Due Date	03-Jun-2003
Petition to Revoke	20-Jun-2003	Due Date	03-Jun-2003
Office Action Received Yet?	23-Jun-2003	Reminder	13-Aug-2002
Petition to Rev Follow Up Date	03-Dec-2003	Due Date	01-Jan-1930
File IDS	12-Dec-2003	Due Date	12-Dec-2003
Petition to Rev Follow Up Date	03-Jan-2004	Reminder	12-Dec-2003
POSTCARD REC'D BACK PTO	12-Jan-2004	Reminder	19-Dec-2003
Petition to rev Follow Up Date	03-Mar-2004	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-Apr-2004	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-May-2004	Reminder	01-Jan-1930
Petition to rev Follow Up Date	03-Jun-2004	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-Jul-2004	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-Aug-2004	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-Sep-2004	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-Oct-2004	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-Nov-2004	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-Dec-2004	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-Jan-2005	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-Feb-2005	Reminder	01-Jan-1930
Petition to Rev Follow Up Date	03-Apr-2005	Reminder	

## EXHIBIT D

Re Application of:

David O'Leary

Due Date: 6/30/03

Mailed: 6/2/03

Mailer: Jin Zhang

RECEIVED

For: Reservoir Pressure System for Medicament Inhaler

Serial No. 09/888,199  
TECHNOLOGY CENTER 5400 No.

Docket: IVAL-127-1  
56327-149  
Office on the date

In the above matter, the following has been received in the U.S. Patent and Trademark Office on the date stamped hereon.

- |  |  |
|--|--|
| <input type="checkbox"/> Specification, Abstract and<br>( ) Claims — ( ) Total Pages | <input type="checkbox"/> Extension of time             |
| <input type="checkbox"/> Declaration and Power                                       | <input type="checkbox"/> Amendment                     |
| <input type="checkbox"/> Drawing ( ) sheets  | <input checked="" type="checkbox"/> Cert. of Mailing   |
| <input type="checkbox"/> Assignment  | <input type="checkbox"/> Maintenance Fee Transmittal   |
| <input type="checkbox"/> Check \$  | <input type="checkbox"/> Affidavit (w/wo Exhibits)     |
| <input type="checkbox"/> Request for Recordation                                     | <input type="checkbox"/> Notice of Appeal              |
| <input type="checkbox"/> Information Disclosure Statement                            | <input type="checkbox"/> Brief ( ) copies              |
| <input type="checkbox"/> Small entity verification                                   | <input type="checkbox"/> Issue fee transmittal         |
| <input checked="" type="checkbox"/> Amendment and Response; Petition to Revive       | <input checked="" type="checkbox"/> Transmittal letter |
| <input type="checkbox"/>   |  |



## Interview Summary

Application No.

09/888,199

Applicant(s)

O'LEARY, DAVID

Examiner

Nihir Patel

Art Unit

3743

All participants (applicant, applicant's representative, PTO personnel):

(1) Nihir Patel. (3) \_\_\_\_\_.

(2) Mark Lappin. (4) \_\_\_\_\_.

Date of Interview: 06-03-03

Type: a) ☐ Telephonic b) ☐ Video Conference  
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: 1.


Identification of prior art discussed: Schaeffer.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The applicant's invention discloses a cup assembly movably received in the channel where as Schaeffer (reference) does not. The application will be considered for allowance upon a further search by the examiner.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

  
Carl D. Price  
Primary Examiner

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
Examiner's signature, if required

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David O'Leary, et al. Examiner: Nihir Patel  
Serial No.: 09/888,199 Group Art Unit: 3743  
Filing Date: June 23, 2001  
Docket Number: 56327-149 (IVAL-127-1)  
Title: RESERVOIR PRESSURE SYSTEM FOR MEDICAMENT INHALER

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**CERTIFICATE OF MAILING (37 C.F.R. 1.8(a))**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Date: \_\_\_\_\_

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Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Sir:

Enclosed herewith for filing in connection with the above-identified patent application are the following:

- 1) Amendment and Response;
- 2) Petition to Revive; and
- 3) Acknowledgment Postcard.

No further fees are believed due; however please charge any fees which may be due, or credit any overpayment, to Deposit Account Number 50-1133.

Respectfully submitted,



Date: 2 JUNE 2003

---

Mark G. Lapping, P.C.  
Registration No.: 26,618  
McDERMOTT, WILL & EMERY  
28 State Street  
Boston, Massachusetts 02109  
Telephone: (617) 535-4043  
Facsimile: (617) 535-3800

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	David O'Leary, et al.	Examiner: Nihir Patel
Serial No.:	09/888,199	Group Art Unit: 3743
Filing Date:	June 23, 2001	
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Title:	RESERVOIR PRESSURE SYSTEM FOR MEDICAMENT INHALER	

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Date: \_\_\_\_\_

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PETITION FOR REVIVAL UNDER 37 CFR §1.137(b)**

Sir:

Applicants respectfully request revival of the subject application in accordance with 37 CFR §1.137(b).

Apparently, an Office Action in the subject application was mailed to the assignee of the Applicants on August 13, 2002. However, the assignee of the Applicants has no record of receiving the Office Action.

On May 20, 2003, the undersigned counsel for the Applicants first received a copy of the Office Action from the above identified examiner during an interview with the examiner at the USPTO in a related application.

The six-month statutory period for response to the Office Action expired February 13, 2003. The delay in filing a timely response to the Office Action was unintentional. A full and complete Response to the Office Action is filed herewith. A Notice of Abandonment has not been received by the Applicants. Applicants respectfully request revival of the subject Application in accordance with 37 CFR §1.137(b).

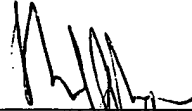
Since the failure to file a timely and proper response to the Office Action dated August

13, 2002 appears to be due to the assignee of the Applicants' failure to receive the Office Action from the USPTO, it is believed no fees are due with respect to the submission of this paper. However, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 50-113.

Date: \_\_\_\_\_

2 JUNE 2003

Respectfully submitted,



---

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